

### **REMARKS**

By this reply, claim 131 has been amended. Claims 1-157 and 159-243 are pending in the application.<sup>1</sup> No new matter has been added by the amendment to claim 131. Reconsideration and allowance are respectfully requested in view of the following remarks.

#### **Personal Interview**

Applicants thank Examiner Oropeza for the courtesies extended to their undersigned representative during the personal interview held on April 28, 2006. Applicants' separate record of the substance of the interview is incorporated in the following remarks.

#### **Election of Species/Restriction Requirement**

According to M.P.E.P. § 821.04(a), once independent claim 131 is found to be allowable, withdrawn dependent claims 132, 134-149, 156, 157 and 159-162 should be rejoined.

The Official Action has withdrawn claim 243 from consideration as being independent or distinct from the invention originally claimed. As was discussed during the personal interview, the subject matter recited in claim 243 is sufficiently similar to the subject matter of claim 131 that any additional search directed to the subject matter of claim 243 would not impose an undue burden on the Office. Accordingly, Applicants respectfully request that the restriction requirement with respect to claim 243 be withdrawn.

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<sup>1</sup> The Office Action Summary indicates that only claims 131, 133, 150-155 and 243 are pending in the application.

**Claim 150**

The Office Action Summary indicates that claim 150 is rejected. However, claim 150 is not rejected in either of the two rejections under 35 U.S.C. § 103(a) set forth at pages 2-5 of the Official Action. Accordingly, Applicants assume that claim 150 is allowable.

**First Rejection Under 35 U.S.C. § 103**

Claims 131, 133 and 151-155 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,713,954 to Rosenberg et al. ("Rosenberg") in view of U.S. Patent No. 4,690,134 to Snyders ("Snyders"). The rejection is respectfully traversed.

Claim 131, as amended, recites a process for assisting the function of a heart having an outer wall and which is disposed within a patient. The claimed process comprises importing at least one value of at least one parameter relating to the function of the heart into a controller; using an algorithm to formulate at least one command instruction, based upon the at least one value of the one parameter; and exporting the at least one command instruction from the controller to assist the heart by effecting changes in volume of a drive fluid within a single continuous cavity of variable volume extending circumferentially completely around the outer wall of the heart. For example, in the embodiment of the DMVA device shown in FIG. 2E, a single continuous cavity between the liner 114 and the inner surface of the shell wall 112 extends circumferentially completely around the outer wall of the heart 30.

As recited in claim 131, the heart is assisted by effecting changes in volume of a drive fluid within the single continuous cavity of variable volume extending

completely circumferentially around the outer wall of the heart. As further recited in claim 131, the process comprises exporting at least one command instruction from a controller to assist the heart by effecting changes in volume of the drive fluid within the single continuous cavity of variable volume.

Applicants respectfully submit that the combination of Rosenberg and Snyders fails to suggest the process recited in claim 131. Rosenberg discloses an extra cardiac ventricular assist device. The device shown in Figure 2 of Rosenberg, for example, includes an artificial myocardium 11 (cuff) connected to an energy converter 19 and a hydraulic reservoir 21. As shown in Figure 3B of Rosenberg, the cuff 11 includes numerous cylindrical tubes connected along their axially extending walls and that together extend completely around the cuff. Each of the multiple tubes of the cuff 11 includes a cavity, and thus the cuff includes numerous separate cavities into which hydraulic fluid is introduced. The cuff 11 does not include a single continuous cavity of variable volume extending circumferentially completely around the outer wall of a heart, as recited in claim 131.

Applicants submit that Rosenberg would have led one having ordinary skill in the art away from the modification proposed in the Office Action. For example, at column 3, lines 41-44, Rosenberg discloses that:

A key concept for this artificial myocardium system is achieved by the realization of a controllable, artificial myocardium employing a cuff formed of a series of closed tubes connected along their axially extending walls. (Emphasis added).

Furthermore, at column 1, lines 58-63, Rosenberg describes the ventricular assist device disclosed in Snyders (and other references) as being of the type that has an elastic inner wall and inelastic outer wall, thereby compressing the myocardium of the ventricle to aid pumping. Applicants submit that the combination

of Rosenberg and Snyders does not suggest modifying Rosenberg's artificial myocardium, which includes a series of tubes, to have a single continuous cavity of variable volume that can extend circumferentially completely around the outer wall of a heart. Accordingly, the applied references would not have rendered obvious the claimed process. Thus, claim 131 is patentable.

Claims 133 and 151-155, which depend from claim 131, are also patentable over Rosenberg for at least the same reasons as those for which claim 131 is patentable. Therefore, withdrawal of the rejection is respectfully requested.

#### **Second Rejection Under 35 U.S.C. § 103**

Claims 131 and 151-155 stand rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 6,626,821 to Kung et al. ("Kung") in view of Snyders. The rejection is respectfully traversed.

Kung discloses a flow-balanced cardiac wrap for enclosing a ventricular region of the heart. The embodiment of the cardiac wrap 110 shown, for example, in Figure 1 of Kung, includes numerous inflation elements 112 arranged in parallel longitudinally. Each of the individual inflation elements 112 defines a separate cavity of variable volume, which is inflatable to apply pressure to the heart 100 on which the wrap 112 is fitted. Kung depicts other embodiments of the wrap in Figures 7-13, 19 and 23-25, for example. Each of these other disclosed embodiments also includes multiple inflation elements, each defining a separate cavity, such that each wrap includes multiple cavities. Kung does not disclose or suggest a wrap including a single continuous cavity of variable volume extending circumferentially completely around the wall of a heart, as recited in claim 131.

As was discussed during the interview, Snyders also does not provide the required suggestion or motivation to modify Kung's cardiac wrap, which includes multiple inflation elements, each defining a separate cavity, to have a single continuous cavity of variable volume that can extend circumferentially completely around the outer wall of a heart. Accordingly, the applied references would not have rendered obvious the claimed process. Thus, claim 131 is patentable.

Claims 133 and 151-155 depend from claim 131 and thus are also patentable over Kung and Snyders. Therefore, withdrawal of the rejection is respectfully requested.

#### **Claim 243**

Applicants request that the restriction requirement with respect to claim 243 be withdrawn, and claim 243 be examined with the elected subject matter.

Claim 243 recites a process for assisting the function of a heart including a left ventricle, a right ventricle and an outer wall, where the heart is disposed within a patient. The process comprises, *inter alia*, "exporting the at least one command instruction from the controller to assist the heart by effecting changes in volume of a drive fluid within a first cavity of variable volume corresponding to the left ventricle and a separate second cavity of variable volume corresponding to the right ventricle, the first and second cavities together extending circumferentially completely around the outer wall" (emphasis added). Applicants submit that Claim 243 is also patentable.

**Conclusion**

For the foregoing reasons, allowance of the application is respectfully requested. Should the Examiner have any questions concerning this response, to expedite prosecution, the Examiner is respectfully requested to contact the undersigned at the number given below.

Respectfully submitted,

BUCHANAN INGERSOLL PC

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